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10/553,603	09/29/2006	Anne-Gaelle Brachet	1169-041	6009

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JUNEAU PARTNERS
333 N Fairfax St.
Suite 305
ALEXANDRIA, VA 22301

EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,603	BRACHET ET AL.	
	Examiner	Art Unit	
	CYNTHIA B. WILDER	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,27,28 and 31-39* is/are pending in the application.

4a) Of the above claim(s) *24,27,28 and 31-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I claims 1-23 and 37-39 in the reply filed on 9/10/2009 is acknowledged. The traversal is on the ground(s) that the restriction is improper because no objection based upon lack of unity was raised during the international phase of the corresponding PCT and because there is clearly unit of invention because the same or special technical feature of the claims is a double stranded DNA adapter AA containing the first bases only (not the entire sequence) of a type IIS restriction enzyme recognition sequence.

The arguments have been thoroughly reviewed and considered but are not found persuasive. Firstly, with regards to Applicant's arguments concerning the unity in the national stage application, it is noted that MPEP states that PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national in national applications filed under 35. USC 111. Therefore, this argument is not found persuasive. With regards to applicant's arguments that the claims correspond to the same technical feature, it is noted that the claims of Groups II and III are sufficiently broad such that they are not limited to the special technical feature argued by Applicant. Likewise, the cited prior art provided evidence that the broadest first named invention was not special and did not provide a contribution over the art. The requirement is still deemed proper and is therefore made FINAL. Claims 1-23 and 37-39 are discussed in this Office action. Claims 24,

27-28, 31-36 are withdrawn from consideration as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.489b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.487(b) and by the fee required under 37 CFR 1.17(i)

Drawings

2. The drawings filed 9/29/2006 are acknowledged. However, the drawing amendments appear to be informal and are not clearly legible. It is suggested submitting formal drawing in response to this Office action.

Specification

3. The disclosure is objected to because of the following informalities:

(a) The specification is objected because it lacks a heading "Brief Description oft he Drawings". Applicant is reminded of the following guidelines which illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

(b) The disclosure is objected through the specification because the designation for the sequence identifier is improper (see MPEP§ 2422.03). It is suggested amending the disclosure by changing "SEQ ID No." to recite --SEQ ID NO:--.

(c) The use of the trademark "AmpliTaq GOLD" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter; *Diamond v. Chakrabaty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated short DNA fragment".

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-23 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-20 and 37-39 are indefinite in the claim 1 because the claims are extremely wordy and do not provide a clear nexus between the preamble and steps. It cannot be determined what is required to actually prepare the DNA fragments as recited in the preamble. Likewise it cannot be determined the relationship between the steps I ("I. for a first selection of short fragments") and II ("II. for a second selection of one or more subset(s) of fragments from the fraction of short fragments F2 obtained in step d)" because it cannot be determined if the I. and II are intended to be active method steps

or something else. Given the ambiguity of the claims as currently written, a clear interpretation of Applicant's intent cannot be ascertained.

(b) Claims 1-20 and 37-39 is indefinite in the claim 1 at "capable of randomly fragmenting the sample of nucleic acid" because it cannot be determined if the limitation after "capable of" is a property of the enzyme E1 or is intended to be an active step. It is suggested amending the claims such that the method recites an active steps by changing "capable of randomly fragmenting the sample of nucleic acid" to --which randomly fragments the sample of nucleic acid--.

(c) Claims 1-20 and 37-39 are indefinite and confusing in claim 1 at "so as to form a unit" because it cannot be determined what is meant by "forming a unit". The limitation is not defined in the instant specification and a clear interpretation of Applicant's intent cannot be ascertained.

(d) Claim 1-23 and 37-39 is indefinite and confusing in the claim 1 and claim 21 at "N-x" and "$1 \leq x \leq N-1$" because it cannot be determined what N-x represents or what $1 \leq x \leq N-1$ represents. Clarification is required.

(d) Claims 1-23 and 37-39 is indefinite and confusing in the claim 1 and claim 21 at the dash lines "-" located throughout the claims because it is unclear what the dash lines represent or what is required. Clarification is required.

(e) Claim 2 is indefinite and confusing at "the 3' end of E1a restriction site is that of the unit as defined in step (b)" because the end of the unit is not clearly defined in the step (b) of claim 1 and thus it cannot be determined what is required.

(f) Claim 6 is indefinite and confusing at "purifying the fragments less than 1000 bp" because the claim 1 from which the claim 6 depends do not require that any specific lengths be obtained and thus it cannot be determined how one is to determine which fragments are less than 1000 bp.

(f) Claim 7 lacks proper antecedent basis for "the strand A" because no strand A is recited in the steps I from which the claim depends. Thus, it cannot be determined what Applicant is making reference to.

(g) The claim 7 is indefinite at the recitation of "zone 1" because it cannot be determined what Applicant is making reference to or what constitutes a zone in the context of the claims.

(h) Claims 8 and 10 are indefinite at the recitation of "the zone 1" and a "zone 2" because the claim 1 does not recite because the claim 1 from which the claim depends do not recite any zones and thus it cannot be determined what Applicant is making reference to or what constitutes a zone in the context of the claims.

(i) Claim 15 is indefinite and confusing for the limitations within parentheses because it cannot be determined if the limitations within parentheses are intended to define the claim or is a separate entity. It is suggested that the claims be amended to avoid the parenthetical and clarify what is required.

(j) Claim 21-23 are indefinite in the claim 21 because the claim is extremely wordy and thus a clear interpretation of the structure of the DNA fragment cannot be envisioned. Additionally it cannot be determine what is meant by "representing a genetic marker" because it cannot be determine if Applicant is suggesting that the "short

DNA fragment" is a genetic marker or comprises a sequence which is a genetic marker or something entirely different. The claim overall is confusing. Clarification is required.

Claim Rejections - 35 USC § 102(b)

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Note* -Given the ambiguity of the claims as discussed above, for the purpose of application of prior art, the claims are given the broadest reasonable interpretation by the Examiner.

9. Claims 1-4, 6-23 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Sapolsky et al (20030008292, January 2003).

With regards to claims 1-4, 6-23 and 37-39, these claims are drawn to a method comprising: preparing double stranded DNA fragments using at least one restriction enzyme to generate DNA fragments with blunt or cohesive ends; ligating the ends of said fragments to an adaptor comprising a recognition site for the restriction enzyme, the cleavage site of which is located downstream of said recognition site; cleaving the fragments at the 5'end using a restriction enzyme and purifying said fragments. The claims optionally include additional adapters, amplification of the fragments linked to said adapters with suitable primers. The claims encompass appropriate labels and immobilization to a solid support.

Sapolsky et al teach such a method as pages 2-9 and in the Figures 2 and 3. Therefore, Sapolsky et al meet the limitations of the claims as broadly written.

10. Claims 1-4, 6-23 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (2002/0072055 A2, June 13, 2002).

With regards to claims 1-4, 6-23 and 37-39, these claims are drawn to a method comprising: preparing double stranded DNA fragments using at least one restriction enzyme to generate DNA fragments with blunt or cohesive ends; ligating the ends of said fragments to an adaptor comprising a recognition site for the restriction enzyme, the cleavage site of which is located downstream of said recognition site; cleaving the fragments at the 5'end using a restriction enzyme and purifying said fragments. The claims optionally include additional adapters, amplification of the fragments linked to said adapters with suitable primers. The claims encompass appropriate labels and immobilization to a solid support.

Jones teaches such a method as pages 5-16 and in the Figures 1-4. Therefore, Jones meets the limitations of the claims as broadly written.

11. Claims 1-4, 6-23 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al (WO 0234939, May 2002). With regards to claims 1-4, 6-23 and 37-39, these claims are drawn to a method comprising: preparing double stranded DNA fragments using at least one restriction enzyme to generate DNA fragments with blunt or cohesive ends; ligating the ends of said fragments to an adaptor comprising a

recognition site for the restriction enzyme, the cleavage site of which is located downstream of said recognition site; cleaving the fragments at the 5'end using a restriction enzyme and purifying said fragments. The claims optionally include additional adapters, amplification of the fragments linked to said adapters with suitable primers. The claims encompass appropriate labels and immobilization to a solid support.

Yu et al teaches such a method as pages 5-6 and 11-15. Therefore, Yu et al meet the limitations of the claims as broadly written.

12. Claims 1-4, 6-23 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Eijk et al (WO 0149882, July 2001). With regards to claims 1-4, 6-23 and 37-39, these claims are drawn to a method comprising: preparing double stranded DNA fragments using at least one restriction enzyme to generate DNA fragments with blunt or cohesive ends; ligating the ends of said fragments to an adaptor comprising a recognition site for the restriction enzyme, the cleavage site of which is located downstream of said recognition site; cleaving the fragments at the 5'end using a restriction enzyme and purifying said fragments. The claims optionally include additional adapters, amplification of the fragments linked to said adapters with suitable primers. The claims encompass appropriate labels and immobilization to a solid support.

Van Eijk et al et al teaches such a method as pages 1-10, 24-25 and 27-28. See also Figures 1-3. Therefore, Van Eijk et al meet the limitations of the claims as broadly written.

13. Claims 1-4, 6-23 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato (EP 0735144, October 1996, citation made of record on IDS). With regards to claims 1-4, 6-23 and 37-39, these claims are drawn to a method comprising: preparing double stranded DNA fragments using at least one restriction enzyme to generate DNA fragments with blunt or cohesive ends; ligating the ends of said fragments to an adaptor comprising a recognition site for the restriction enzyme, the cleavage site of which is located downstream of said recognition site; cleaving the fragments at the 5'end using a restriction enzyme and purifying said fragments. The claims optionally include additional adapters, amplification of the fragments linked to said adapters with suitable primers. The claims encompass appropriate labels and immobilization to a solid support.

Kato teaches such a method as pages 5-6 and 11-13. See also Figures 1-3. Therefore, Kato meets the limitations of the claims as broadly written.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Sapolsky et al, Jones, Yu, or Van Eijk et al as previously described above in view of Keith et al (US 5093245). With regards to claim 5, this claim is drawn to a method as described and rejected above, further wherein the steps (a) and (b) are carried out simultaneously.

None of the references previous discussed above teach wherein the steps of restriction digestion and ligation of the fragments are simultaneously prepared.

Keith et al teach et al discloses a method of simultaneously preparing DNA fragments by restriction enzyme digest and ligating said fragments to another nucleic acid of desired function (see column 2-6).

One of ordinary skill in the art would have been motivated to have modified the method of any one of the primary reference by carrying out the preparation and ligation steps simultaneously because Keith discloses the convenience and benefits of simultaneous restriction digestion of DNA and ligation of digestion fragments to another nucleic acid of desired function. It would have been prima facie obvious to one of

ordinary skill in the art at the time of the claimed invention to carry out the claimed method with a reasonable expectation of success.

Conclusion

17. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia B. Wilder/

Examiner, Art Unit 1637